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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/627,114
Filing Date: July 25, 2003
Appellant(s): ZILLA ET AL.

James H. Ackley
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed July 28, 2009, appealing from the Office action mailed June 30, 2008.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

(9) Grounds of Rejection

The following grounds of rejection are applicable to the appealed claims:

Claims 71, 72, 74, 77, 78, 84, and 103-105 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Starling et al., WO 98/43558 A1, which a collagen casing with bridges (page 13, lines 8-9; page 25, lines 32-33) and optional additional coatings (page 14, lines 14-17) to define a composite scaffold containing interconnecting, uniformly shaped spherical pores occupied by an aggregate of bonded hollow microspheres (page 9, lines 4-7; page 13, lines 4-8; page 14, lines 13-14; page 25, lines 21-23; etc.) forming an ingrowth matrix (page 13, lines 26-31) comprising a concentration gradient of growth factors or other pharmaceutical agents (page 13, lines 17-19 and 23-24; page 33, lines 10-14 and 26-27), wherein varying concentrations within the aggregate or ingrowth matrix are designed to perform the specific functions of driving the diffusion and release of growth factors, anti-inflammatory agents, and/or anti-tumor agents (page 13, lines 11-13 and 15-17; page 16, lines 28-30) and facilitating tissue ingrowth (page 13, lines 26-31).

Claims 71-87 and 103-105 are rejected under 35 U.S.C. 103(a) as being unpatentable over Starling et al., WO 98/43558 A1. Because the device can be used in the repair and augmentation of cartilage defects as well as bony defects (page 14, lines 6-8), an implant in the form of, for example, a bone screw having different pharmaceutical agent concentrations for localized treatment of soft and hard tissues would have been obvious from page 12, lines 3-4; page 13, lines 21-22; and so on in order to optimize tissue growth and integration. Regarding claim 73, hydrogels would have been obvious in order to provide greater control over the release

of one or more of the substances. The further limitations of claims 75, 76, and 79-81 would have been obvious materials for facilitating tissue replacement of microsphere structure. Regarding claim 82, helically oriented channels (among other channels) generally follow along and just under the surfaces of the thread(s) of the aforementioned bone screw because of the interconnectivity of the porosities (page 8, lines 28-31; page 12, lines 31-33; etc.) and the hollow microspheres (page 5, lines 7-8; etc.) forming said helical thread(s). Regarding claim 83, the particular range would have been obvious from the ranges specified at page 12, line 29, through page 13, line 3, and from the fact that smaller sizes can be used for soft tissue (page 14, lines 7-8). Regarding claims 85-87, the Starling et al. implant materials being incorporated into the sewing ring of a prosthetic heart valve, for example, would have been obvious to the ordinary practitioner in order to utilize the advantageous properties for tissue treatment and integration at the corresponding heart valve annulus.

(10) Response to Argument

The Appellant's main argument is that "Starling is absolutely silent as to any design including a concentration gradient of a material or a resulting gradient that would involve one concentration having any specific function over another" (Appeal Brief of July 28, 2009: sentence bridging pages 4 and 5). But concentration gradients of each pharmaceutical agent in the Starling et al. biomedical implant are necessarily present, since otherwise outward diffusion of the agent would not be possible. And the varying *growth factor* concentrations play the dual role of driving release of the growth factor and sustaining ingrowth of cells, with each role falling within the scope of "specific functions", as evidenced by the Appellant's own disclosed examples (Appellant's specification: page 5, last sentence). Moreover, "varying concentrations"

(Appellant's claim 71, line 5) are not necessarily confined to a single material, because "comprising" (Appellant's claim 71, line 1) is open-ended or inclusive (MPEP § 2111.03). Varying concentrations of different agents in a Starling at al. implant impart different functions according to the respective innate chemical properties of each agent. The Appellant's assertions with regard to present claim 82 are deemed to be adequately addressed in the grounds of rejection presented above.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/David H Willse/

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